REMARKS

Claims 10-12 are pending in the instant application. Claims 10-12 have been rejected. Claim 10 has been canceled and new claim 16 has been added. Claims 11 and 12 have been amended in light of the cancellation of claim 10 and the addition of claim 16. No new matter has been added. Reconsideration is respectfully requested in light of these amendments and the following remarks.

I. Rejection of Claims 10-12 under 35 U.S.C. § 112, first paragraph - Lack of Enablement

Claims 10-12 have been rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The Examiner suggests that it is not clear how ovarian or testicular cancer serum samples could be distinguished from other cancer types in light of the teachings of Abe et al. regarding elevated PLA2 concentrations in serum for a variety of cancer types, the teachings of U.S. Patent 5,747,264 regarding patients with prostate cancer and prostatitis with PLA2 concentrations in serum

at least two standard deviations above normal male controls, and the teachings of Yamashita et al. regarding lung, breast, esophageal, colorectal, liver, bile duct and pancreatic cancer samples exhibiting levels of PLA2 greater than at least two standard deviations above normal control.

Applicants respectfully traverse this rejection.

At the outset, Applicants respectfully disagree with the Examiner's characterization of the references of Abe et al. and U.S. Patent 5,747,264 as suggestive of a standard deviation of 1 ng/ml of PLA2 as neither of these references provide the data required to accurately calculate standard deviation.

Further, Applicants respectfully disagree with the Examiner's suggestion that because a marker is taught to be useful in diagnosing other types of cancer, it cannot be useful in diagnosing previously undisclosed types of cancer. Diagnostic assays such as serum PLA2 levels are used by physicians along with a battery of other tests including physical examination to arrive at an accurate diagnosis.

However, in an earnest effort to advance the prosecution of this case, Applicants have amended the claims to clarify that the methods are used in monitoring progression of ovarian and testicular cancer in patients. Specifically, claim 10 has been

canceled and new claim 16 has been added which is drawn to a method of monitoring progression of ovarian or testicular cancer in a patient comprising measuring PLA_2 levels in biological samples obtained from a patient at selected times and comparing the measured PLA2 levels wherein an increase in the measured levels of PLA_2 in the patient over time is indicative of progressive ovarian or testicular cancer, a decrease in the measured levels of PLA_2 in the patient over time is indicative of remission or response to therapy of the ovarian or testicular cancer and no change in the measured levels of PLA_2 in the patient over time is indicative of stabilization of the ovarian or testicular cancer. Claims 11 and 12 have been amended in light of the cancellation of claim 10 and the addition of claim 16. Support for claim 16 and amendments to claims 11 and 12 can be found in the specification at page 15, lines 5-24, and in Table 2 at page 14. Accordingly, no new matter has been added by these amendments. Further, one of skill in the art is clearly enabled by the teachings of the specification to make and use the invention as set forth in the amended claims.

Withdrawal of this rejection under 35 U.S.C. § 112, first paragraph, for lack of enablement is therefore respectfully requested.

II. Rejection of Claims 10-12 under 35 U.S.C. § 112, first paragraph - Written Description

Claims 10-12 have been rejected under 35 U.S.C. § 112, first paragraph, as the Examiner suggests that the specification does not contain a written description of the claimed invention. Specifically, the Examiner suggest that the limitation of "levels of PLA2 at least two standard deviations above levels of PLA2 determined in random healthy males or females" has no clear support in the specification and claims as originally filed.

Applicants respectfully traverse this rejection as teachings that PLA2 levels are compared with levels of PLA2 in healthy males and females are provided throughout the specification.

However, in an earnest effort to advance the prosecution of this case, Applicants have canceled claim 10 containing this phrase and represented the claimed invention in new claim 16. Claim 16 does not contain the phrase "levels of PLA2 at least two standard deviations above levels of PLA2 determined in random healthy males or females".

Accordingly, withdrawal of this rejection under 35 U.S.C. 112, first paragraph, for lack of written description, is respectfully requested.

III. Conclusion

Applicants believe that the foregoing comprises a full and complete response to the Office Action of record. Accordingly, favorable reconsideration and subsequent allowance of the pending claims is earnestly solicited.

Attached hereto is a marked-up version of the changes made to the specification and claims by the current amendment. The attached page is captioned "**VERSION WITH MARKINGS TO SHOW CHANGES MADE**."

Respectfully submitted,

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VERSION WITH MARKINGS TO SHOW CHANGES MADE

In the Claims:

Please cancel claim 10.

Please amend claims 11 and 12 as follows:

11. (amended) The method of claim ~~10~~ 16 wherein the biological ~~fluid is~~ samples are serum.

12. (amended) The method of claim ~~10~~ 16 wherein PLA_2 is ~~detected~~ measured by ELISA.